CLAIMS

1. Excipient for dry powder inhalation preparations comprising granules made of primary carrier material, which granules break down during inhalation in such a manner that they give a concentration of primary carrier material at stage 2 of the twin stage impinger of at least 5%, which excipient is obtainable by granulating a primary carrier material in a fluid binding agent and drying the granules thus obtained.

2. Excipient as claimed in claim 1, wherein the concentration of primary carrier material at stage 2 of the twin stage impinger is at least 10%.

3. Excipient as claimed in claim 1 or 2, wherein the concentration of primary ca rrier material at stage 2 of the twin stage impinger is at least 20%.

4. Excipient as claimed in any one of the claims 1-3, wherein the fluid binding agent is an aqueous solution of the primary carrier material.

5. Excipient as claimed in any one of the claims 1-3, wherein the fluid binding agent is a solvent, in particular ethanol.

6. Excipient as claimed in any one of the claims 1-3, wherein the fluid binding agent is water.

7. Excipient as claimed in any one of the claims 1-6, wherein the drying is performed in an oven.

8. Excipient as claimed in any one of the claims 1-6, wherein the drying is performed while the granules are kept in motion, such as in a fluid bed dryer.

9. Excipient according to any one of the claims 1-8, wherein the particle size of the granules lies between 50-1000µm.

10. Excipient according to any one of the claims 1-9,

wherein the particle size of the granules lies between 200-500µm.

11. Excipient according to any one of the claims 1-10, wherein the primary particle median geometric size of the granules lies in the range 1-170µm.

12. Excipient according to any one of the claims 1-11, wherein the primary particle size median geometric size of the granules lies in the range 1-15µm.

13. Excipient acoording to any one of the claims 1-12, wherein the primary carrier material is a monosaccharide, such as glucose, fructose, mannose; a polyol derived from these monosaccharides, such as sorbitol, mannitol or their monohydrates; a disaccharide, such as lactose, maltose, sucrose, a polyol derived from these disaccharides, such as lactitol, manitol, or their monohydrates; an oligo or polysaccharide, such as dextrins and starches.

14. Excipient according to any one of the claims 1-13, wherein the primary carrier material is a crystalline sugar such as glucose, lactose, fructose, manitol or sucrose.

15. Excipient according to any one of the claims 1-14, wherein the primary carrier material of the granules is lactose.

16. A dry powder inhalation formulation which contains a pharmacologically active component and an excipient according to any one of the claims 1-15, for delivery of the active component to the lungs.

17. A dry powder inhalation formulation according to claim 16, in which the active component is selected from the group consisting of steroids, bronchodilators, cromoglycate, proteins, peptides and mucolytics.

18. A dry powder inhalation formulation according to claim 16, in which the active component is selected from the group consisting of hypnotics, sedatives, analgesics, anti-

inflammatory agents, anti-histamines, anti-convulscents, muscle relaxants, anti-spasmodics, anti-bacterials, anti-biotics, cardiovascular agents, hypoglycaemic agents.

19. Method for producing an excipient as claimed in any one of the claims 1-16, comprising granulating a primary carrier material in a fluid binding agent and drying the granules thus obtained.

20. Method as claimed in claim 19, wherein the fluid binding agent is an aqueous solution of the primary carrier material.

21. Method as claimed in claim 19, wherein the fluid binding agent is a solvent, in particular ethanol.

22. Method as claimed in claim 19, wherein the fluid binding agent is water.

23. Method as claimed in any one of the claims 19-22, wherein the drying is performed in an oven.

24. Method as claimed in any one of the claims 19-22, wherein the drying is performed while the granules are kept in motion, such as in a fluid bed dryer.

25. Lactose granules for use in dry powder inhalation preparations, **characterized in that** the granules break down during inhalation in such a manner that they give a concentration of primary carrier material at stage 2 of the twin stage impinger of at least 5%, preferably at least 10%, more preferably at least 20%.

26. Use of an excipient as claimed in claims 19-24 for the preparation of a dry powder inhalation preparation for the treatment of diseases of the respiratory tract.